

## GUIDELINES FOR REVIEWER'S WRITTEN COMMENTS NIDDK SMALL GRANTS FOR UNDERREPRESENTED INVESTIGATORS

The R03 award enable the applicant to accept a tenure-earning position, gain additional research experience while transitioning to independence, and obtain preliminary data on which to base a subsequent research grant application in order to transition to independent investigator status. Refer to the NIH Guide announcements (PAR-02-032, 12/6/01) for more detail about the award. The format outlined below should be followed in preparing your comments for each R03 application assigned to you. Include additional headings when they seem appropriate to the review. If this is an amended application, address progress, changes, and responses to the critique from the previous review, indicating whether the application is improved, the same as, or worse than the previous submission. However, you are not constrained to address only the points identified in the previous review. These comments on progress and/or responsiveness to previous critiques may be provided either in a separate paragraph and/or under the appropriate criteria.

### FOR PRIMARY AND SECONDARY REVIEWERS:

**Resume:** In a brief paragraph, indicate the major strengths and weaknesses of the proposed program as a means of enhancing the investigator's research career and how these factors determine your overall merit rating of the application.

**CRITIQUE:** Address each of the following five criteria as separate sections within the context of the stage of the investigator's career.

**DISCUSSANTS** The written critique for a discussant review may be brief; all aspects of the five review criteria do not need to be specifically addressed. A brief paragraph highlighting the strengths and weaknesses of the application or bulleted lists of strengths and weaknesses are both examples of acceptable critiques. If you prefer to prepare a full critique equivalent to a primary or secondary review, you also have that option.

**(1) Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**(2) Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

**(3) Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

**(4) Investigators:** Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? Do not include descriptive biographical information.

**(5) Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support? Do not describe available facilities and equipment.

**Career Plan and Objectives:** Evaluate how this award would contribute to the applicant's development as an independent scientist, based on the long-term career plans and objectives.

Availability of a Recognized Expert: Although this is not a mentored award, applicants are required to have available a recognized expert in the area of their proposed research for guidance and consultation. A letter indicating their willingness to provide counsel and advice from this recognized expert must accompany the application, along with his or her current biographical sketch. Evaluate the plan to maintain ongoing communication with the application and the whether the expert's area of research is appropriate for the research goals and career objectives of the applicant.

Action: The application may be recommended for no further consideration, deferred in order to obtain additional information, or given a priority score. If the application is to be scored, indicate the level of scientific merit using the adjectival scale.

Budget: Comment on the appropriateness and justification of the budget request within the context of the goal of the award. Up to \$100,000 per year, in modules of \$25,000, is allowed.

OTHER CONSIDERATIONS: If these matters affect the assessment of the scientific merit of the application, they will be considered as part of the critique and the overall score.

Involvement of Human Subjects: Explain concerns regarding the proposed use of human subjects, including any possible physical, psychological, or social injury individuals might experience while participating as subjects in the research. Indicate whether their rights and welfare will be protected adequately or whether they may be subjected to ethically questionable procedures. Determine if an appropriate balance of gender and minority representation in the study population will be sought, if this is scientifically acceptable, and justify the gender and minority codes to be assigned. Determine whether children (individuals under 21 years of age) have been included in the research and if their inclusion or exclusion has been explained adequately to justify the code to be assigned. If a data and safety monitoring plan is required, indicate if it is adequate. For additional information, refer to the "NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications."

Animal Welfare: If animals are to be used in the project, discuss if their use is justified and if they will be given proper care and humane treatment so that they will not suffer unnecessary discomfort, pain, or injury.

Model Organism Sharing Plan: All NIH applications that plan to produce new, genetically modified variants of model organisms and related resources are expected to include a sharing plan or to state why such sharing is restricted or not possible. Please comment on the adequacy of the sharing plan, taking into consideration the organism, the timeline, and the applicant's decision to distribute the resource or deposit it in a repository. Your assessment of the sharing plan will not be factored into the priority score of the application. Your comments will be captured in an administrative note.

Hazardous Materials and Procedures: Describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.